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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,703	05/01/2001	Mark W. Kroll	A01P1028	6988

7590 06/04/2003  
PACESETTER, INC.  
15900 Valley View Court  
Sylmar, CA 91392-9221

EXAMINER

OROPEZA, FRANCES P

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 06/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/847,703

Applicant(s)

KROLL, MARK W.

Examiner

Frances P. Oropeza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 3/11/03 (Amendment).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 March 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION**

***Claim Rejections - 35 USC § 103***

1. Claims 1, 3, 6-8, 10, 15-20 and 25-30 are rejected under 35 U.S.C. 102(e) as anticipated by Maarse (US 6128535) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Maarse (US 6128535) in view of Yerich et al. (US 6456878).

As to claims 1, 18, and 27, the right and left ventricles are synchronously stimulated by a pulse generator (18) on demand (col. 4 @ 66 – col. 5 @ 12; col. 5 @ 23-25; col. 8 @ 53-55; col. 6 @ 50 – col. 7 @ 2). It is inherent the right ventricular electrode (32) in the right ventricle (30) is located on a right ventricular lead and the left ventricular electrode (36) in the left ventricle (figure 2; col. 6 @ 50-59). Capture is verified (col. 7 @ 3-12).

As to claims 2, 9 and 22, bi-atrial and bi-ventricular pacing and sensing is disclosed (col. 2 @ 44-52; col. 5 @ 23-32).

As to claims 3, 6, 10, and 19, the selected polarities of the electrodes of the activation stimulation sequence controls the activation path; the activation site, read as the site receiving the positive pulse, is the right ventricle. The left ventricle receives the negative pulse (col. 7 @ 43-54 and 58-62; col. 3 @ 31-34).

As to claim 7, a first and second right ventricular electrodes verify the capture (col. 2 @ 44-52; col. 3 @ 31-34).

As to claim 8, 20 and 28, the at least two electrodes are read as four electrodes, two for pacing and two for sensing (col. 2 @ 44-52; col. 3 @ 31-34; col. 5 @ 23-32).

As to claims 13, 14, 23 and 24, one ventricular chamber is paced and the other ventricular chamber is sensed. The right and left chambers are used for sensed and paced or paced and sensed respectively depending on the configuration (col. 2 @ 44-52; col. 3 @ 31-34).

As to claim 15, a left atrial electrode is inherently located on a left atrial lead and AV sequential pacing is enabled by sensing a myoelectrical signal between the left atrial electrode and the right ventricular electrode (col. 2 @ 44-52; col. 6 @ 22-25).

As to claim 16, 17, 25, 26, 29 and 30, capture is confirmed by detecting an evoked response/ depolarization and loss of capture is confirmed by not detecting an evoked response/ depolarization (col. 7 @ 26-30). When capture is tested during an intrinsic rhythm, the presence of an intrinsic rhythm following a stimulation pulse confirms loss of capture (col. 7 @ 12-15; col. 3 @ 11-15 and 25-28).

In the alternative, Yerich et al. teach multi-chamber cardiac pacing systems using an atrial lead and two ventricular leads containing electrodes for the purpose of physically supporting and positioning the electrodes at space apart site of a patient's heart to enable sensing and pacing of the heart. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used an atrial and two ventricular leads to containing electrodes in the Maarse system in order to provide pacing sequences and confirm the effectiveness of the pacing sequences so conduction defects of diseased hearts are corrected optimizing the cardiac output (figure 2; col. 1 @ 39-61; col. 3 @ 18-25).

2. Claims 2, 9, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maarse (US 6128535) in view of Yerich et al. (US 6456878), or, in the alternative, under 35 U.S.C. 103(a) as obvious over Maarse (US 6128535) in view of Yerich et al. (US 6456878) and

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further in view of Yerich et al. (US 6456878). As discussed in paragraph 1 of this action, Maarse discloses the claimed invention except for the leads comprising tip and ring electrodes where the tip electrodes are used for stimulation (claims 2, 9, 22) and the ring electrodes are used for sensing (claim 9, 22).

Yerich et al. teach multi-chamber cardiac pacing systems using ring and tip electrodes on the atrial lead and on the ventricular leads for the purpose of enabling pacing and sensing, respectively, at space apart site of a patient's heart. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used using a ring and a tip electrodes on the atrial lead and on the ventricular leads in the Maarse system in order to provide and confirm the effectiveness of pacing sequences to address the conduction defects of diseased hearts (figure 2; col. 1 @ 39-61; col. 3 @ 18-25; col. 7 @ 31-49).

3. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maarse (US 6128535) in view of Sullivan et al. (US 6208895) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Maarse (US 6128535) in view of Yerich et al. (US 6456878) and further in view of Sullivan et al. (US 6208895). As discussed in paragraph 1 of this action, Maarse discloses the claimed invention except for the delivered pulses being mono-phasic and biphasic.

Sullivan et al. teach pacing circuitry using mono-phasic or biphasic pulses for the purpose of generating stimulation waveforms to correct life-threatening cardiac conditions. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used monophasic or biphasic pulses in the Maarse system in order to treat ventricular fibrillation using the historically proven stimulation waveform (mono-phasic) or a waveforms (biphasic) that

potentially lessens heart trauma associated with the pulse, so the optimum waveform can be identified and utilized to treat the patient (col. 1 @ 6-21 and 35-42; col. 2 @ 21-29).

4. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Maarse (US 6128535) in view of Yerich et al. (US 6456878) and further in view of KenKnight et al. (US 6169921) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Maarse (US 6128535) in view of Yerich et al. (US 6456878) and further in view of Yerich et al. (US 6456878) and further in view of KenKnight (US 6169921). As discussed in paragraphs 1 and 2 of this action, modified Maarse discloses the claimed invention except for verifying capture using impedance measurements.

KenKnight et al. teaches capture determination using impedance / voltage differential for the purpose attenuating cardiac polarization voltages to effectively determining if a pacing stimulus results in heart capture or contraction. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used impedance / voltage differential to detect capture in the modified Maarse system in order to provide a more accurate means to verify capture that is not negatively impacted by patient activity, body position, noise and saturation voltages and to provide a capture verification method that minimizes the number of required components of the stimulation system (abstract; col. 3 @ 44-53; col. 4 @ 35-41; col. 11 @ 34-62).

5. Claims 12-14, 21, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maarse (US 6128535) in view of KenKnight et al. (US 6169921) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Maarse (US 6128535) in view of Yerich et al.

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(US 6456878) and further in view of KenKnight et al (US 6169921). As discussed in paragraph 1 of this action, Maarse discloses the claimed invention except for verifying capture using impedance measurements (claim 12, 21) or voltage differential (claims 13, 14, 23, 24).

KenKnight et al. teaches capture determination using impedance / voltage differential for the purpose attenuating cardiac polarization voltages to effectively determining if a pacing stimulus results in heart capture or contraction. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used impedance / voltage differential to detect capture in the Maarse system in order to provide a more accurate means to verify capture that is not negatively impacted by patient activity, body position, noise and saturation voltages and to provide a capture verification method that minimizes the number of required component of the stimulation system (abstract; col. 3 @ 44-53; col. 4 @ 35-41; col. 11 @ 34-62).

#### ***Statutory Basis***

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the

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organization where this application or proceeding is assigned is (703) 306-4520 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist, telephone number is (703) 308-0858.

Frances P. Oropeza  
Patent Examiner  
Art Unit 3762

*FPO*  
*5-22-03*

*Angela D. Sykes*

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